[12013/49401]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	Gerald FREDRICKSON
Serial No.	:	10/670,819
Filed	:	September 24, 2003
For	:	AN ULTRASONIC NOZZLE FOR COATING A MEDICAL APPLIANCE AND METHOD FOR USING AN ULTRASONIC NOZZLE TO COAT A MEDICAL APPLIANCE
Examiner	:	John Frederick Parker
Art Unit	:	1762
Customer No.	:	26646

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

S I R:

I, Gerald Fredrickson, declare and state as follows:

1. I am the named inventor of the above-captioned application.

2. I conceived of the subject matter described and claimed in the above-captioned application prior to March 19, 2003.

3. Attached hereto as Exhibit 1 is a copy of a document entitled "BSC Invention Disclosure," which was prepared and submitted to patent counsel for Boston Scientific Corporation, prior to March 19, 2003. Exhibit 1 has been partially redacted to remove certain date information.

4. I exercised diligence in constructively reducing to practice the subject matter described and claimed in the above-captioned application from at least a time prior to March 19, 2003, continuously up to September 24, 2003, the date on which the above-captioned application was filed in the United States Patent and Trademark Office. During that time, I provided information to patent counsel for preparation of the above-captioned application and reviewed and revised drafts of the above-captioned application.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 35 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2-15-05

Gerald Fredrickson

BSC INVENTION DISCLOSURE

Boston Scientific Corporation
One Boston Scientific Place, Natick, MA 01760-1537

DISCLOSURE # 03-D0232
Date Received:
Team Code:
- For Legal Dept. use only -

TITLE

Air Suspension Coater for Processing Delicate Medical Devices

DIVISION: Molecular Interventions

INVENTORS

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(Note: *Please do not witness until all of the inventors have signed off*)

WITNESS
(Read & Understood)

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Kathi A Mercier 3/13/03
Signature & Date

ABSTRACT & FIGURES
(Please summarize the background and technical novelties of your idea)

Problem:

Air suspension is a process by which a large number of stents can be freely suspended in a nitrogen gas stream as a coating is efficiently applied and dried all in one process. Two of the issues facing air suspension are the effect of the process on the mechanical integrity of the stent as well as the effect on the coating. As new more flexible stent designs are developed these issues become more critical.

One reason for potential damage to occur to the stent and the coating is the velocity of the stent as it is fluidized. This velocity can damage the stent and coating as it impacts other stents and the inside of the vessel. The velocity is mostly the result of the atomizing pressure used to atomize the coating. If this pressure could be reduced or eliminated then damage would be reduced or eliminated.

Solution:

One solution for this problem is to atomize the coating by a different less forceful method. If the current air atomizing nozzle is replaced with an ultrasonic nozzle, which uses no air pressure for atomization, then the major source of stent velocity has been eliminated.

Improvements Over State of the Art

Current state of the art for air suspension involves the use of an air atomizing spray nozzle mounted at the base of the hurricade vessel. In order to obtain efficient coating it is necessary to mount the nozzle at the base to maximize the transfer of coating to the stents. The issue with mounting the spray nozzle at the base is that the direction of the spray is straight up. This direction is the same as that of the fluidization gas, which keeps the stents, fluidized. The problem is that the atomization pressure is highly focused and tends to shoot the stents with high velocity when they pass over the spray nozzle.

The improvement of using an ultrasonic coating nozzle is that no atomizing pressure is required. This eliminates the highly focused jet and the shooting of stents at high velocity. There is sufficient gas flow from fluidization flow to distribute the atomized coating and keep the stents fluidized.

Keywords: air suspension, stent, coating

INVENTION DETAIL & PREFERRED EMBODIMENTS

In detail, please describe the specific novel features of your idea/invention including, design, operation, process, and method of use. Please attach any relevant figures, sketches, diagrams, AutoCAD drawings, notebook pages, and any other supporting material that supplements your idea/invention. Please include an index of figures if necessary.

Novelty:

The present air suspension system utilizes an air atomizing spray nozzle, which imparts a jet of gas, which can shoot stents at rapid speeds and cause both coating and stent damage. The use of an ultrasonic atomizing nozzle does not require this jet of atomizing air. Therefore, this type of coating system would be ideal for delicate items such as stents.

Design:

There are three possible variations of the design.

1.) The nozzle could be mounted at the base of the hurricade with the tip facing up into the hurricade.

2.) The nozzle could be mounted through the side of the hurricade with the tip inserted through a side port and being centered in the diameter of the cross section of the vessel.

3.) The nozzle could be mounted through the top of the hurricade vessel with the tip centered in the top and protruding down to the base of the hurricade.

Materials:

The nozzle could be made out of any acceptable materials currently used for ultrasonic nozzles that are also solvent resistant. This would include such metals as stainless steel and titanium. The remainder of the air suspension equipment would be constructed of current materials such as stainless steel.

Preferred Embodiment:

The nozzle would be most effective if mounted from the bottom or side where the tip could be placed closest to the vessel base.

Method of Use:

This unit could be used to coat delicate stents as well as other small medical devices requiring coating.

Enablement:

A commercially available ultrasonic nozzle can be fitted to an existing air suspension unit. Some minor modifications to the unit are expected.

BACKGROUND

Briefly discuss the problem, disease condition, and existing devices, therapies, and process. Please highlight the specific advantages and the novelty of your idea/invention. Cite and attach any relevant references, articles, patents, and notebook pages.

Existing Devices:

ALTERNATE EMBODIMENTS

Please disclose any possible alternate embodiments of your idea/invention addressing the following points: Designs, applications, materials, coatings, uses, accessories, construction processes, costs, etc. Please assess the applicability of your idea/invention with other BSC products, procedures, and processes.

Alternate # 1

CONSTRUCTION DETAILS

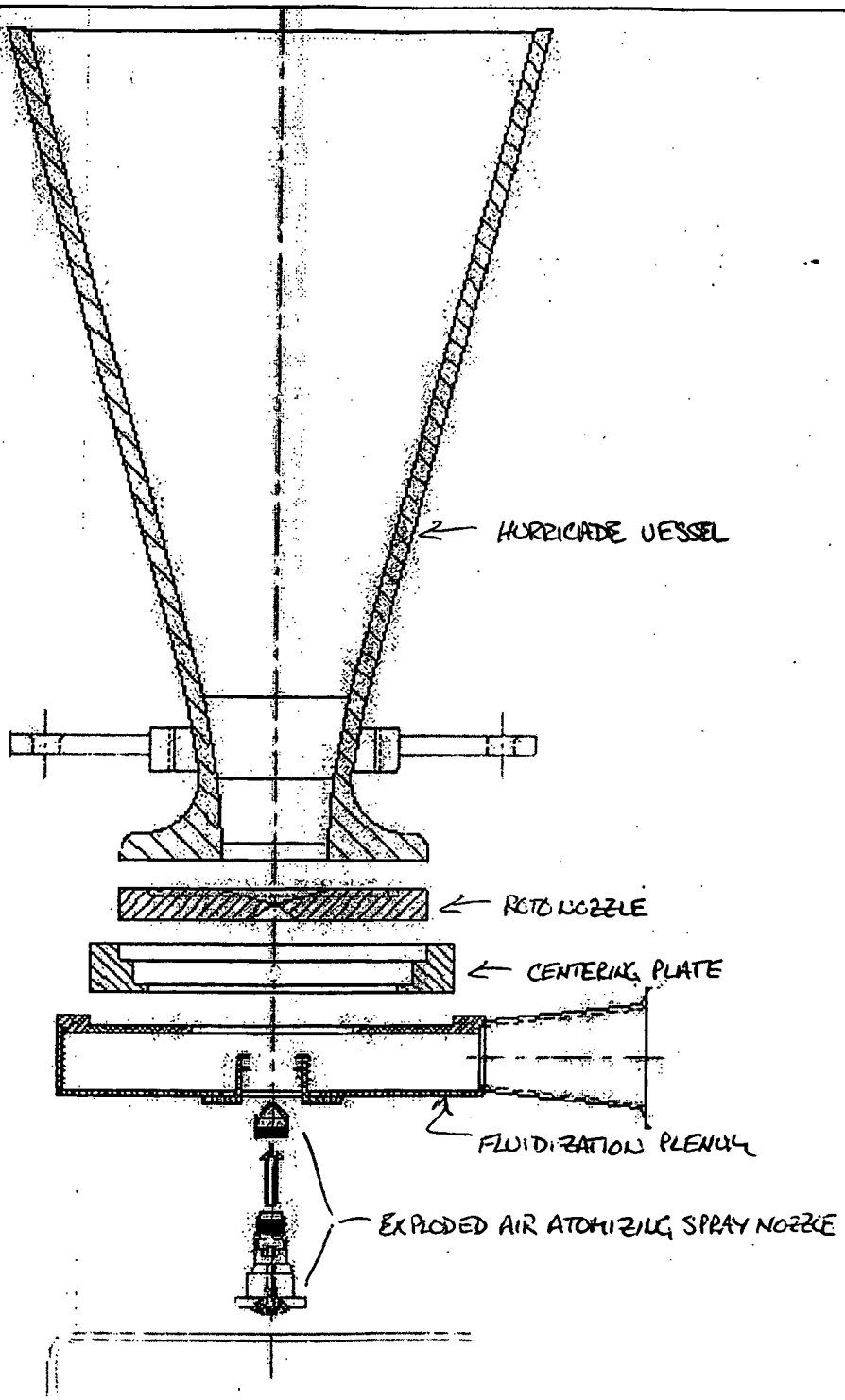
Please disclose, in detail, the manufacture of your invention/idea, highlighting factors such as speed, simplicity, repeatability, accuracy, lower costs, location, etc.

SUPPLEMENTARY INFORMATION

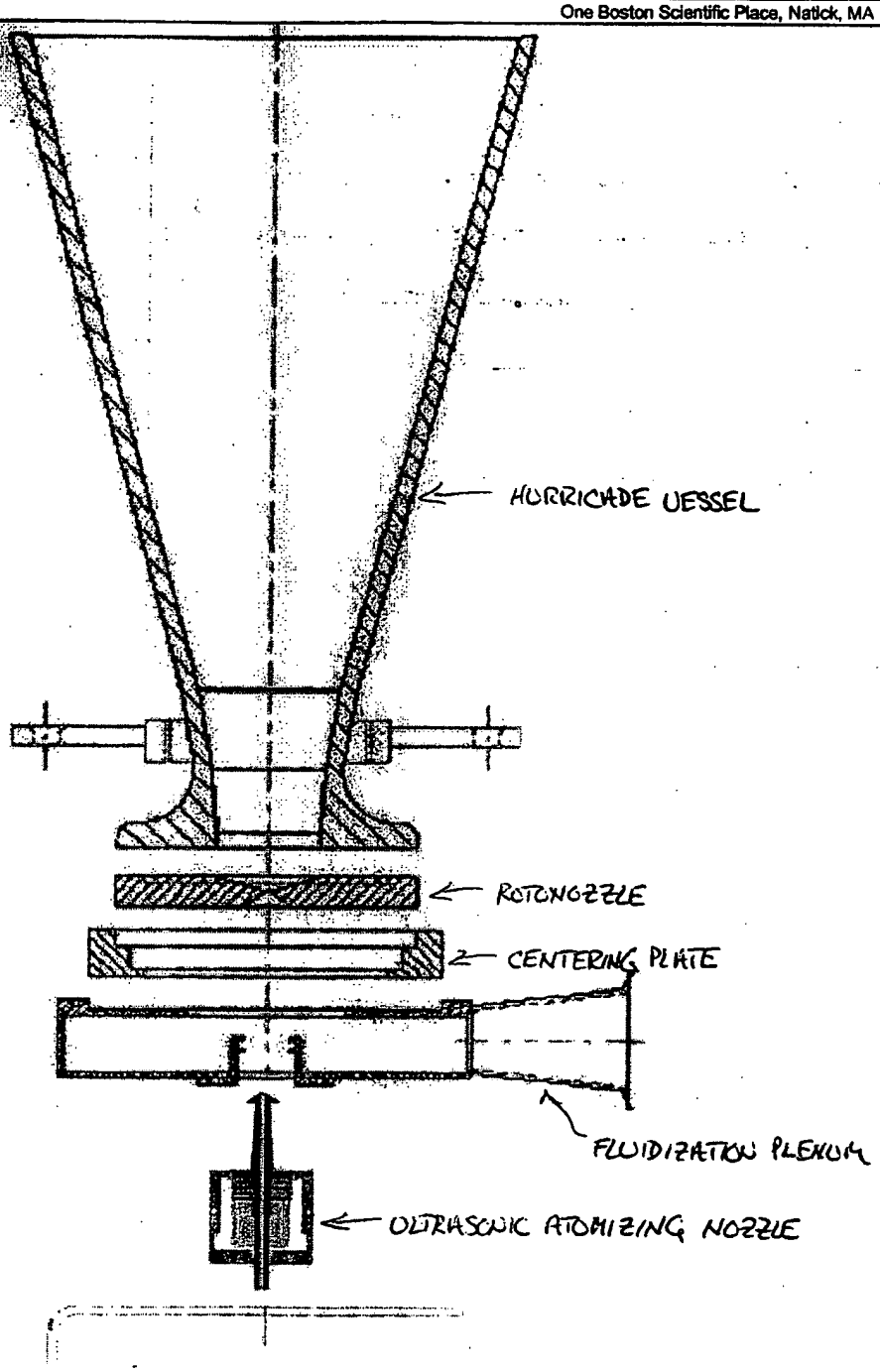
In addition to a copy of your notebook pages, please attach or describe any relevant supplementary information, including journal articles abstracts, reports, package inserts, marketing information, ets.

FIGURES

Please sketch any drawings and figures of your invention/idea demonstrating applicability, ease of use, construction, etc. (Please use additional pages as needed).



Air Suspension cross section with an air atomizing spray nozzle



Air suspension cross section with the preferred location of the ultrasonic atomizing nozzle

BSC INVENTION DISCLOSURE

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GENERAL INFORMATION

Documentation of Idea:

Please reference your lab notebook and pages that document your invention/idea.

Lab Notebook No. ___N 0451_____; Page No. ___68-69____

If different, date of first known drawings: _____

Who has custody of drawings? ___G Fredrickson_____

Please list the dates and names of BSC employees to whom and when you have disclosed your invention/idea.
M.J. Timm Steve Spencer Kathi Mercier

Prototype:

Please note the date you first began building your first prototype/model: not yet

Please note the date and particulars of the first test of your invention/idea: Date: not yet
(Please attach, summarize or reference a report of the test results)

Please list the names of witnesses who saw the prototype:

Project Phase:

What is the current project phase? (concept, development or scale-up) Development

Product release date: _____

Engineering Project Number: _____117640 or X1239_____

Date of disclosure outside of BSC: _____*not yet*_____ ***(Please list the names and Organizations below)***

If you are aware of any publications, presentations, or patents that pertains to your idea please contact the Legal Department.

Boston Scientific Corporation
One Boston Scientific Place, Natick, MA 01760-1537

Guidelines for Protecting BSC Innovations

Purpose

To ensure diligent recording of ideas and effective filing of patent applications

Rationale

A powerful patent position is crucial to the continued survival and profitability of BSC. Patents can only be obtained, and later effectively enforced, by following the strict discipline of recording and disclosing ideas, as well as filing patent applications on valuable ideas. All BSC employees, especially engineering staff are strongly encouraged to understand and follow the process of protecting BSC innovations.

General Guidelines

When you conceive of a new idea, for example a novel catheter design, a novel processing algorithm or a better manufacturing method, or even a unique packaging design, the first thing you should do is write it down, preferably in your engineering notebook. You should then have the notebook or other document page(s) signed and dated by at least one witness. Preferably two people will witness your idea, one who may not understand the idea but witnesses the document's existence and one who does understand the idea, is not a co-innovator and not likely to become a co-innovator. These documents will be useful to the patent attorney/agent who writes your patent application, and later, these documents will be crucial to prove that you were the first to conceive of the idea.

Periodically you should review your engineering notebook with your supervisor to assess the value of all your ideas. If your supervisor and you feel that an idea is unique and should be protected, you should fill out the attached "Idea Disclosure" form and submit it to the on-site patent representative. The attached Idea Disclosure Form is detailed and designed to help you provide relevant information. Feel free to add any additional information you believe is helpful. The appropriate Patent Review Board will then review your Idea Disclosure and determine whether to pursue a patent application, retain the idea as a trade secret, submit a defensive publication or request further development. If the Patent Review Board decides to file a patent application, the Invention Disclosure and any other material you provide will then be forwarded to a patent attorney/agent assigned to write your patent application. A meeting may be scheduled for you and the assigned patent attorney to review the Idea Disclosure. The more detailed your idea disclosure, the more prepared the patent attorney/agent will be prior to your meeting and the better the quality of the subsequent application.

It takes at least 1 year and typically 2 to 3 years before a patent is issued. During this period, numerous correspondences will be sent back and forth between the patent office and the patent attorney/agent (and BSC) to clarify the patentability of the application. Effective communication with the patent office is vital to eliminating obstacles and obtaining allowed claims. The patent attorney/agent plays an important role in making this happen.

Once the patent attorney successfully negotiates with the patent office to obtain allowed claims, BSC will pay an issue fee. A patent number is assigned shortly after receiving the fee, but it then takes about 3 to 6 additional months for the patent to be published and for BSC to receive the actual hard copy patent. Once published, BSC can begin enforcing the patent.